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REMARKS

We thank the Examiner for taking time for the interview of September 13, 2006.¹

Applicants' submit herewith a Declaration of Leon Hirsch. This Declaration constitutes evidence of secondary considerations of non-obviousness including:

- 1) evidence of commercial success;
- 2) evidence of copying by competitors;
- 3) evidence of long felt need in the industry; and
- 4) evidence comprising laudatory statements by competitors.

Any one of the four categories of secondary consideration evidence may show the non-obviousness of the claims. Accordingly, each of the four categories deserve separate consideration with regard to the claims.

I. EVIDENCE OF COMMERCIAL SUCCESS***High Commercial Success Despite Name Recognition or Advertising***

As discussed in the Declaration, the open ear hearing aid system described and claimed in the above-referenced application was first commercially launched by the assignee of this application, Vivatone Hearing Systems, LLC ("Vivatone"), in the first quarter of 2004, and is embodied in products designated the "Vivatone Mini", the "Vivatone Standard" or the "Vivatone Dual". At the time of the open ear hearing aid commercial launch, Vivatone, as a small startup company whose product line consisted solely of the open ear hearing aid product, did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivatone did not engage in any television

¹ In the Interview Summary sheet, the Examiner stated her belief that the term "open configuration" is vague. For the record, Applicant does not acquiesce to this characterization of the term; and indeed, Applicant believes that the term "open ear configuration" has a clear and distinct meaning to persons of ordinary skill in the relevant hearing aid art.

or radio advertising, and only minimal other national advertising. National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal. Notwithstanding the lack of name recognition and advertising, Vivotone's open ear hearing aid has achieved a high degree of commercial success.

Notwithstanding the lack of name recognition and advertising, Vivotone's open ear hearing aid has achieved a high degree of commercial success. As may be seen from the sales charts at Exhibit 2, domestic unit sales and domestic net revenues have steadily increased from the first quarter of 2004 until December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivotone's open ear hearing aid went from no sales to almost eighteen million dollars. Those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.

The claims correlate with the commercial embodiment and should therefore be attributed the commercial success derived therefrom

The following shows the necessary nexus between the commercial device and the claims at issue and provides additional assurance that the commercial success indicia should not be rebutted, discounted or diminished, but instead should rebut any prima facie case of obviousness (alone or together with the discussed long felt need, laudatory statements and copying secondary considerations).

As noted above, notwithstanding extremely minimal advertising efforts and the lack of name recognition, Vivotone has achieved a high degree of commercial success. As may be seen from the sales charts at Exhibit 2, domestic unit sales and domestic net revenues have steadily increased from the first quarter of 2004 until December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivotone's open ear hearing aid went from no sales to almost eighteen million dollars. Those sales

came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.

The law relating to commercial success evidence

In relevant part, the law with regard to commercial success indicates that evidence that a commercial product, which is covered by a claim, has significant commercial success indicates that the inventor went beyond the application of ordinary skill (thus obviating a *prima facie* case of obviousness with regard to the claimed matter). See *Tennant Co. v. Hako Minuteman, Inc.*, 22 USPQ2d 1161, 1177 (N.D. Ill. 1991) ("If, upon incorporating the invention in its products, the patentee captures a large market share, or if most competitors either license or copy the invention, that tends to show that the patented article is significantly better than existing substitutes and one may infer that it represents a nonobvious advance over the prior art...if the patented invention has a significant commercial impact, that suggests that the inventor went beyond the application of ordinary skill."). See *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353, 1361, 52 USPQ2d 1294, 1299 (Fed. Cir. 1999) ("a *prima facie* case of nexus is generally made out when the patentee shows both that there is a commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.* ... (Fed. Cir. 1988). The evidence shows that [the patentee] sold approximately two million fans per month, all of which were made according to the patented method. See *Akzo N.V. v. United States Int'l Trade Comm'n* ... (Fed. Cir. 1986) (finding commercial success where a product made by a patented method was commercially successful.)").

While some courts have allowed rebuttal of such commercial success evidence, this is limited to circumstances where either the commercial success is related to extensive advertising or name recognition, or the commercialized product is not covered by a claim. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679, 7 USPQ2d 1315, 1318 (Fed. Cir. 1998) (the district court erred in finding that the requisite "nexus" between the commercial success of the patentee's pad and the merits of the patented

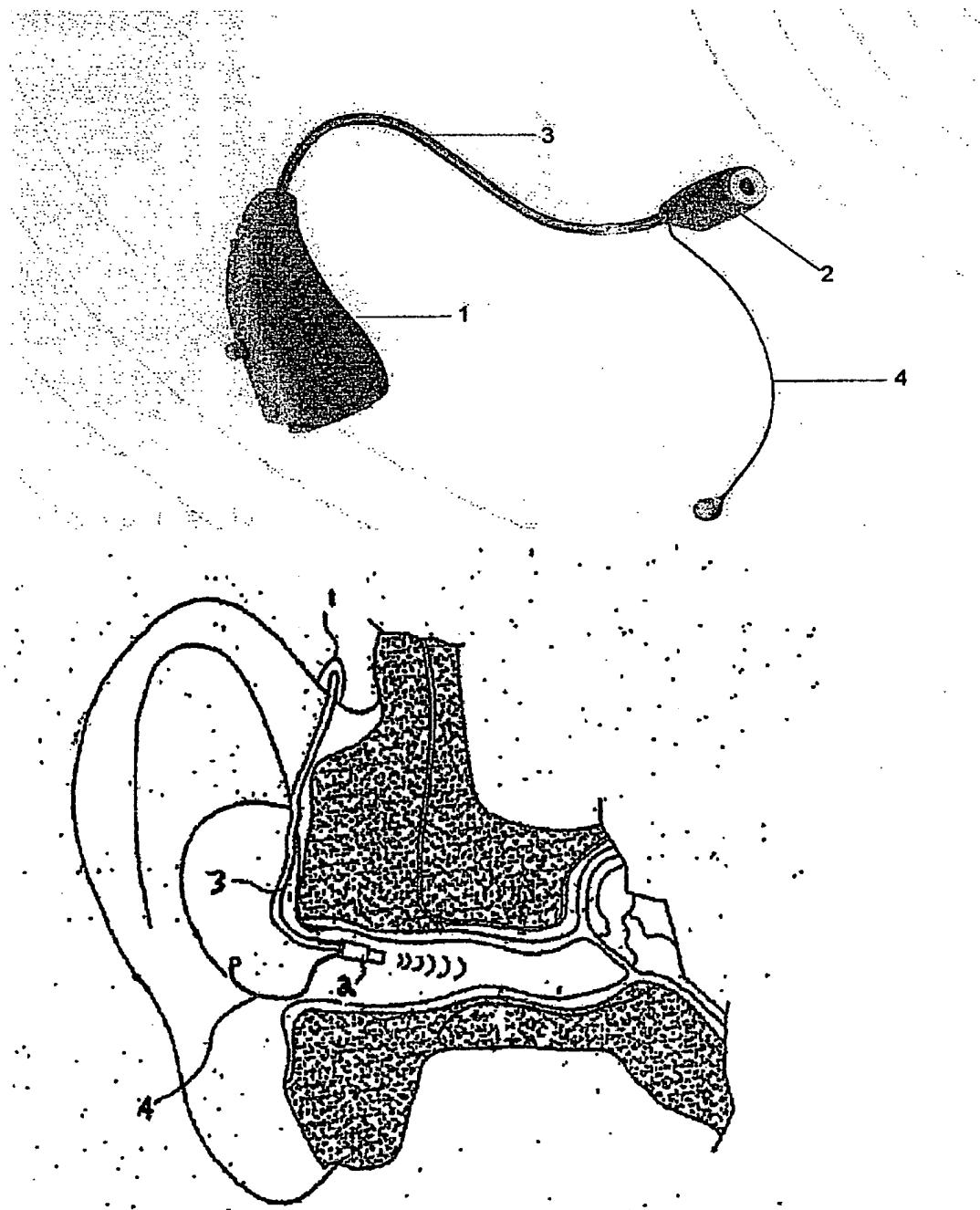
invention had not been established; there was no finding or evidence “of extraneous factors such as advertising or superior workmanship to rebut the patentee’s evidence of substantial commercial sales, and sales growth, of the patented pad...”); *Pro-Mold and Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1574, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996) (the patentee’s “lack of previous experience in the relevant market combined with it’s high sales of the patented product provided an inference of a nexus between it’s commercial success and the patented invention and are thus probative evidence of nonobviousness. Its lack of market power in this field would seem to suggest that it was the features of the patented invention that led to the commercial success.”); *Compare McNeil-PPC, Inc. v. Perrigo Co.*, 337 F.3d 1362, 1370 (Fed. Cir. 2003) (affirming district court finding that a patent owner “had launched a massive marketing and advertising campaign in connection with the launch of [its] product, obscuring any nexus that might have existed between the merits of the product and its commercial success.”) and *McNeil-PPC, Inc. v L. Perrigo Co.*, 207 F. Supp.2d 356, 364, 365 n.21, 372, 63 USPQ2d 1493 (E.D. Pa. 2002), aff’d in part, rev’d in part, 337 F.3d 1362, 1370 (Fed. Cir. 2003). (noting a patent owner’s “a massive \$45 million marketing and advertising campaign”; a later “sales increase correspond[ed] with an increase in advertising expenditures.”); AGGRESSIVE MARKETING: the patent owner’s “sales [were] the calculated result of an aggressive marketing campaign of unprecedented scope.”); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.* ... (Fed. Cir. 1988).

As discussed above, Vivotone was completely unknown prior to introduction of its open ear hearing aid system. Accordingly, name recognition cannot come into play to challenge the evidence of nonobviousness. Also, Vivotone’s advertising was extremely minimal (as noted above, Vivotone did not engage in any television or radio advertising, and only minimal other national advertising; National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal.).

Comparison of Independent Claim 1 with the Vivotone commercial device

Reference is made to the following images of the commercial Vivotone device as an aid to review of the following claim chart:

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The following claim chart relates aspects of independent claim 1 of Vivotone hearing aid to the commercialized Vivotone hearing aid to which the above-described commercial success figures above relate. Relevant portions of the independent claims (which portions are substantially reproduced in the remaining independent claims) are reproduced below:

A hearing aid, comprising: a microphone sampling position located externally of an ear canal of a user;	The Vivotone hearing aid includes a microphone and microphone port located within the behind-the-ear component (1).
a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal;	The receiver (2) comprises a speaker (5) provided within the ear canal in an open ear configuration and is suspended within the ear canal by virtue of the stiffness of the intermediate wire (3) and/or the effect of the concha wire (4).
wherein sound from the microphone sampling position is amplified and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;	The sampled sounds are passed to an amplifier provided in the behind the ear component (1) and are relayed to the speaker (5) via the intermediate wire (3), which is provided around a portion of the external ear into the ear canal opening.
wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit	The microphone port and amplifier are both contained within the behind the ear component (1).

Further, as noted in the Declaration, the additional aspect of independent claim 1 is also embodied in the commercial Vivotone device, including the receiver generating about three decibels or below of insertion loss over a portion of human ear audible frequencies.

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II. EVIDENCE OF COPYING, LONG FELT NEED, AND LAUDATORY STATEMENTS BY COMPETITORS

Vivatone's Novel Open Ear Hearing Aid System

Vivatone's novel open ear hearing aid system configuration minimizes insertion loss and occlusion effect and uses the ear's natural "receiver" to the fullest, mixing natural sound and amplified sounds in the ear for excellent sound clarity (see the Declaration of Leon Hirsch, Vivatone Hearing Systems brochure, Exhibit 2).

Vivatone's open ear hearing aid system resolves the biggest problems that hearing aid wearers experienced prior to the introduction of the Vivatone hearing aid solution: occlusion, insertion loss, feedback and resonance effects (depending on the type of hearing aid used). Occlusion is the "head in the barrel" effect created when the hearing aid wearer speaks or chews. Feedback is the whistling sound experienced when a patient places a telephone near the ear or other structure. Feedback is similar to the whistling sometimes heard in an auditorium when the microphone is too close to the speaker. Further, BTE devices feeding sound to the ear canal via a sound tube suffer from resonance effects. Vivatone revolutionized hearing aids by developing a product that eliminates the *long felt need* with regard to each of these annoyances. That is, Vivatone enhances hearing while enabling the wearer to enjoy normal speaking, eating or telephone conversation without interference.

The reason that Vivatone hearing aids are able to provide these benefits is its unique design. Vivatone's microphone is housed in a small plastic case located behind the ear. *Unlike other hearing aids, Vivatone delivers sound from the microphone sampling position behind the ear electronically to its speaker in the ear canal. The speaker is suspended in the ear canal and is small enough to allow the ear canal to remain open, and therefore, is non-occluding.* This revolutionary approach has advanced the acceptance of hearing aids significantly. As noted, prior to Vivatone, hearing aids either significantly occluded the ear canal or transmitted sound from a speaker located behind the ear to the ear canal through a plastic tube. These designs

cause either occlusion or insertion loss or distortion or lack of clarity. Vivotone's open ear speaker allows the patient's residual natural sound to combine with the enhanced hearing provided by Vivotone's processor, giving crisp, clear sound to the patient.

Background On Prior Types Of Hearing Aid Devices

It is interesting to note that various types of hearing aids, including BTE (behind-the-ear), CIC (completely-in-canal), ITE (in-the-ear) and ITC (in-the-canal) have been in the marketplace for 30 or more years. These types of hearing aids are well known. BTE hearing aids house all electronics in a unit nested behind the ear of a wearer and use a sound tube to pipe amplified sound waves into the ear canal. *While the profile of the sound tubes are generally small within the ear canal, resonances created by the sound tubing is problematic* (see Oticon's discussion of the problems of sound tubing in BTE systems, Declaration of Leon Hirsch, Delta Audiology Concept, Exhibit 5, page 4). The remaining prior hearing aid devices, CIC, ITE and ITC, significantly occlude the ear canal. ITE and ITC hearing aids contain all of the electronics and are molded to the outer ear and/or the ear canal. ITE and ITC hearing aids are typically cosmetically apparent to people around the wearer. CIC hearing aids also contain all of the electronics, but are provided deep within the ear canal, such that a viewer does not see the housing (some sort of pull wire is typically used to withdraw the CIC).

As noted by Oticon's discussion of CIC hearing aids, Declaration of Leon Hirsch, Delta Audiology Concept, Exhibit 5, page 4, "*...even where a collection vent is used with a CIC, the deep insertion of a CIC does not allow for a totally occlusion free fitting...[and] [t]he resulting occlusion is often enough to limit the acceptance of traditional technology for this particular group.*"

Long Felt Need in the Industry Reflected by the Long Delay to the Open Ear Solution

Thus, despite the fact that BTE, CIC, ITE and ITC hearing aids have been available for decades, it was only between 2002 and 2004 (that is, between Vivotone's application for patent and introduction of a commercial open ear hearing aid system) with

the introduction of the Vivotone's hearing aid system that a truly open ear hearing aid system shedding all of the disadvantages of the BTE, CIC, ITE and ITC devices was introduced to the industry. Thus, it took decades for the hearing aid industry to create Vivotone's novel open ear hearing aid system innovation.

While the open ear hearing aid system described by Vivotone's claims took decades to create, it is significant that the above types of hearing aids, and indeed, vented CIC units per se, have been known. Thus, despite the fact that vented CIC units were known, no other company in the field of hearing aids were motivated to separate the electronics from the speaker in the ear canal and place the electronics in a behind the ear unit, electrically connected to the open ear receiver, until Vivotone did so. It is reasonable to conclude that on this evidence alone, (that is, the fact that it took many years for a company to incorporate provide such an arrangement as did Vivotone despite the fact that vented CIC units were well known), it would not have been obvious to provide a hearing aid device with behind the ear electronics connected to an open ear receiver suspended within the ear canal or to modify the teachings the cited art to provide for such open ear configuration.

The Substantial Copying of Vivotone's Open Ear Configuration by Large, Well-Known Competitors Along with Substantial Laudatory Evidence by those Companies

We also note that, since the release of Vivotone's commercial product, there has been *substantial copying* of Vivotone's open ear configuration by the large, well-known hearing aid companies. Also, as will be discussed in more detail below, these large, well known companies have been *aggressively marketing* (i.e., numerous and overtly pointed comments relating to) *the open ear aspects, which have been copied* from the Vivotone device and that are described in the pending independent claims.

For example, in February, 2006, approximately 25 months after the introduction of the Vivotone's open ear hearing aid system (note that while Vivotone's sales were \$27,000 in the first quarter, over the course of two years, sales amounted to almost eighteen million dollars), a direct competitor of Vivotone introduced the Oticon "Delta" hearing aid, (hereafter referred to as the "Oticon Delta") (See the Oticon stock exchange

announcement at Exhibit 3, dated February 1, 2006). Oticon is a large, famous and internationally well known hearing aid manufacturer doing over five hundred million dollars (\$500,000,000) a year generally in hearing aid sales. As described below, the Oticon Delta includes Vivotone's open ear hearing aid invention. Also, the Oticon marketing literature related to the Oticon Delta continually highlights aspects of Vivotone's open ear hearing aid invention as an extremely significant advance in the hearing aid field. More than that, Oticon uses it's marketing literature in conjunction with it's well known name in the hearing aid industry and, despite Vivotone's prior sales, claims to be the "first hearing aid device in a new category – RITE" (or Receiver in the Ear") (See Declaration of Leon Hirsch, Oticon Delta web page captures at Exhibit 4).

Exhibits 3 – 6 from the Declaration of Leon Hirsch provide various announcements, web page captures and product brochures from the Oticon web site, which describe the Oticon Delta hearing aid as newly providing the hearing aid industry with the next generation of communications solutions in the RITE (Receiver In The Ear) category. The February 1, 2006 Oticon's stock exchange announcement (Exhibit 3) describes the Oticon Delta as consisting "of two units connected by an ultra-thin, almost invisible copper wire." The announcement goes on to state, "This copper wire connects a newly developed speaker placed inside the ear canal with a small, triangular, digital amplifier placed discretely behind the ear." Oticon's announcement also practically mirror's the present application's specification language as well as Vivotone's brochure language when it states, "By moving the electronics parts behind the ear, we have made room for a completely open solution, without compromising the cosmetic and audiological advantages of the in-the-ear hearing aids." As is clear, for example from Exhibit 3, the Oticon Delta is the same open ear hearing aid system as is embodied by the Vivotone open ear hearing aid system, for which a patent was presently applied for more than 35 months prior to the announcement of the Oticon Delta and for which the Vivotone product was commercially available more than 25 months prior to the announcement of Oticon Delta. This is *clear evidence of copying* in the industry, and as will be described below, *clear evidence of laudatory remarks of our novel open ear aspects by competitors that have copied us in the marketplace*.

Specifically referencing the presently pending independent claim 1, which is reproduced in relevant part above, *the marketing literature for Oticon Delta exactly embodies the bulk of the limitations within the claim. Also, our tests of the Oticon Delta have further shown that the Delta meets the limitation requiring about three decibels or below of insertion loss over a portion of human audible frequencies.*

Referring specifically to the Oticon brochure entitled ‘Delta’s Audiology Concept’, Exhibit 5, Oticon states, “With Delta’s innovative design, we were able to place the microphones and battery behind the ear in an extremely discrete shell-set and place the Receiver In The Ear (RITE).” Referring specifically to the Oticon Delta design description on Oticon’s website, Exhibit 6, the behind the ear unit (1) includes the digital amplifier and microphone sampling ports. The BTE unit connects to the speaker (3), which is in the ear canal, via a thin sound wire (2). The receiver (3) is suspended in the ear canal with their open dome, which includes three arms extending radially away from the speaker toward the ear canal walls (as noted in the Delta Audiology Concept brochure, Exhibit 5, the “open dome used in Delta provides for the same acoustic response as an open ear, thus providing total occlusion relief.”) (note also that the same brochure contrasts the open ear configuration with use of vents in CIC (completely in canal) hearing aids by noting, “...even with a collection vent, the deep insertion of a CIC does not allow for a totally occlusion free fitting...the resulting occlusion is often enough to limit the acceptance of traditional technology for this very particular group.”) *Based on the foregoing, all of the elements in the independent claims of the above-referenced application are copied by the Oticon Delta device and are lauded by the Oticon Delta marketing literature.* Since the Vivotone hearing aid was launched in the commercial market more than 2 years prior to the launch of the Oticon Delta, *it is evident that Oticon Delta copied Vivotone’s open ear hearing aid system innovation.*

Further, it is significant that *each and every* mention of the new Oticon Delta includes laudatory statements regarding the benefits of the open ear configuration (that is, a BTE combined with an open ear RITE) thus supporting the nonobviousness of the presently pending claims.

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Reference is made to the Declaration of Leon Hirsch, which itemizes just some of Oticon's numerous laudatory remarks relative to the benefits of the open ear system, including separating the amplifier from the speaker, positioning of the BTE relative to the open ear receiver and using a thin wire to connect the two:

<u>Exhibit</u>	<u>Statement</u>
3	“... belongs to a new generation of communication solutions in the RITE (Receiver-In-The-Ear) category”
4	<i>“Delta is the first hearing device in a new category - RITE”</i>
5 p.4	“... takes full advantage of...a totally open fitting” “Unique to the Delta design, the receiver is placed in the ear canal...” “...placing the receiver in the ear canal removes the need to compensate for the resonances created by the sound tubing...” “Clearly, the best solution is to bypass the need for compensation and corrections and to place the receiver in the ear canal...” “...the optimum solution is to implement a unique way of providing sound to the ear canal...One that combines the occlusion free properties of a BTE with the sound quality and cosmetic benefits of a CIC...” <i>“With Delta’s innovative design, we were able to place the microphones and battery behind the ear in an extremely discrete shell-set and place the Receiver In The Ear (RITE style).”</i> “...same acoustic response as an open ear, thus providing total occlusion relief...”
p.10	<i>“To ensure that occlusion is never an issue, Delta provides a totally open fitting concept, allowing the balanced mix of natural and amplified sound.”</i>

"...the receiver has been placed in the ear canal where tube resonances and other sound quality limitations of traditional tubing are not a factor."

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"...placed in the ear canal to offer unmatched performance and comfort..."

The Law Regarding Copying and Laudatory Comments by Competitors

Referencing the law concerning *copying and laudatory comments* by the industry, numerous Federal Circuit decisions have approved reliance on copying by competitors and laudatory statements by competitors as good and strong evidence of non-obviousness (as will be discussed below, particularly with regard to Vivotone's circumstances). Thus, the law requires that the Examiner give patentable weight to this evidence of copying and laudatory statement evidence. See *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988) ("Copying is additional evidence of nonobviousness"); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679, 7 USPQ 2d 1315, 1319 (Fed. Cir. 1988) (Copying is an indicium of nonobviousness, and is to be given proper weight."); *National Steel Car, Ltd. v. Canadian Pacific Railway, Ltd.*, 254 F.Supp.2d 527, 570 (E.D. Pa. 2003) ("Copying by others of the design of the . . . Patent is a relevant secondary consideration to the obviousness determination."); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997) (noting that infringer's recognition of importance of invention is objective evidence of non-obviousness) (before this litigation, [the infringer] recognized calibration during dialysis as a significant advance. [It] touted the advantages of UTO-ADJUST, as it termed automatic recalibration during dialysis, in the advertising for the allegedly infringing. . . machines. [Its] recognition of the importance of this advance is relevant to a determination of nonobviousness."); *Allen Archery Inc. v. Browning Mfg. Co.*, 2 USPQ 2d 1490, 1493 (Fed. Cir. 1987) (evidence of praising the advantages in a competitors catalogs is evidence of secondary considerations of non-obviousness); *Tennant Co. v. Hako Minuteman, Inc.*, 22 USPQ2d 1161, 1177 (N.D. Ill. 1991) ("If, upon

incorporating the invention in its products, the patentee captures a large market share, or if most competitors either license or copy the invention, that tends to show that the patented article is significantly better than existing substitutes and one may infer that it represents a nonobvious advance over the prior art...if the patented invention has a significant commercial impact, that suggests that the inventor went beyond the application of ordinary skill.”).

The Law Regarding Long Felt Need in the Industry

It is also noted that such evidence of secondary consideration is particularly persuasive when the claimed aspects alleviate a *long felt need* in the industry. *In re Mahurkar Patent Litigation*, 831 F.Supp. 1354, 1377-78, 28 USPQ2d 1801, 1819 (N.D. Ill. 1993, aff'd, 71 F.3d 1573, 37 USPQ2d 1138 (Fed. Cir. 1995) (“The existance of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence – the kind that can't be bought from a hired expert, the kind that does not depend on fallable memories or doubtful inferences – of the state of knowledge.”); *Gentry Gallery Inc. v. Berkline Corp.*, 939 F. Supp. 98, 104, 41 USPQ2d 1345, 1350-51 (D. Mass. 1996), aff'd in part, rev'd in part, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) (“The most persuasive evidence is that prior to 1990 a substantial need was felt by the public but unsatisfied by the existing range of products and that [the patentee's] imagination and technical ingenuity created a new invention that spoke to that appetite.”).

In the instant case, it is submitted that the evidence submitted herewith supports a conclusion that Oticon (and others, including Hansatone (discussed below)) copied the invention set forth in independent claim 1 (with specific reference to the open ear speaker suspended in the ear canal, the behind the ear amplifier, and the electrical wire connecting the behind the ear component and the open ear receiver, such as is recited in the claims). What makes this evidence so compelling is the fact that Oticon has *repeatedly and continuously* designated the open ear hearing system as a “*new*” and

important feature and as a significant advance (i.e., "new generation"; "new category"; "innovative design") in the field of hearing aids. These laudatory statements exist despite the fact that various different types of hearing aids, including BTE, CIC, ITE and ITC hearing aids, have been known for decades prior to introduction of the Vivotone open ear hearing aid system. It is reasonable to conclude therefore that the presently claimed open ear hearing aid is non-obvious. Had it been obvious, then it would be irrational for Oticon to be highlighting to the commercial public that such feature is "New" or that such features sets forth a significant advance in the field of hearing aids. Indeed, the fact that Oticon highlights these features as being "New" and significant, coupled with the fact that BTE, CIC (even vented CIC units), ITC and ITE hearing aids per se have been known for decades again further evidence that in the field of hearing aids, the idea of this suspended, open ear speaker combined with the behind the ear amplifier and microphone was not obvious until this invention was made by Vivotone.

Other large hearing aid companies have also copied Vivotone's open ear hearing aid. These companies emphasize (i.e., laudatory statements /re) the same features claimed in the instant application (open ear aspects, receiver in the ear, connecting wire and BTE component). For example, another direct competitor of Vivotone, Hansaton, has recently announced a new hearing aid, "Free Soundmanager", (hereafter referred to as the "Hansaton Free") (See the Hansaton web page snapshots at Exhibit 8 of the Declaration of Leon Hirsch). Hansaton is another large, famous and internationally well known hearing aid manufacturer. As described below, the Hansaton Free also includes Vivotone's open ear hearing aid design; and the Hansaton marketing literature related to the Hansaton Free continually and openly highlights Vivotone's open ear hearing aid design as a significant advance in the hearing aid field. More than that, Hansaton uses its marketing literature in conjunction with it's well known name in the hearing aid industry for it's open ear "Hansaton Free" hearing aid.

Referring specifically to the Exhibits attached to the Declaration of Leon Hirsh, Hansaton's March, 2006 press release, Exhibit 7, page 1, describes the consumer interest in the idea of Hansaton's open ear hearing aid system (corresponding to Vivotone's

claimed invention) as follows: "Free VC Open: Delivery has started, the interest and demand from all our customers side is enormous, as well as our backlog of booked orders! We expect to have full ability of supply by mid of April." Exhibit 8, page 1 (web pages describing the Hasatone Free) describes their "Free Soundmanager Natural" as follows:

Experience the future superlative sound with the innovative natural technology. The receiver placed directly in the auditory canal with its almost invisible link enables excellent hearing enjoyment.

Page 2 of Exhibit 8 begins with a large font "OPEN" and follows with the statement, "Open design and maximum wearing comfort – the trademarks of FREE SOUNDMANAGER." The web page goes on to state:

The "open" design of both versions offers you an extremely pleasant wearing comfort and a very natural sound. That's what makes the FREE SOUNDMANAGER stand out from normal hearing systems. It's new design cuts out unpleasant closure effects...

Page 7 of the Hansaton Free hearing aid brochure, Exhibit 9, states that their hearing aid is the "only instrument to combine two benefits...provid[ing] top-of-the-range audiological performance and remain[ing] virtually invisible in the process." Page 9 at Exhibit 8 reiterates in bolded letters, "Open shape and maximum wearing comfort are the trademarks of FREE SOUNDMANAGER." Pages 18-19 at Exhibit 9 again emphasize the "Open" and "External receiver concepts" in large font headings.

There can be no doubt that, with reference to the images of Hansaton Free and with reference to the laudatory language in Hansaton's marketing literature (e.g., "open" and "external receiver"), that the Hansaton Free is the same open ear hearing design as is embodied by the Vivotone open ear hearing aid system (specifically, a behind the ear unit houses an amplifier and a microphone and is connected via an electrical wire to an open

ear speaker suspended within the ear canal), for which a patent was applied for more than three years prior to the announcement of the Hansaton Free and for which the Vivotone product was commercially available more than two years prior to the announcement of Hansaton Free.

We have not tested the Hansaton Free; however, review of the images of the device reveal that the device is remarkably similar to both the Oticon Delta and the Vivotone hearing aids. Accordingly, due to the apparent similarities of the Hansaton Free with the Oticon Delta and the Vivotone hearing aids, we expect that the properties (particularly with regard to the about three decibels or below' insertion loss limitation of independent claim 1) will be similar.

Thus it is apparent that Hansaton, like Oticon, has latched onto the open ear technology (/re Vivotone's product and in the wake of Vivotone's introduction to the market) as being the future, or the next generation, of hearing aid technology and as being the long awaited solution to problems within the industry. Accordingly, we believe this to be clear evidence of copying in the industry, and as will be described below, clear evidence of laudatory remarks of Vivotone's novel open ear aspects by competitors that have copied Vivotone in the marketplace.

It is significant that *each and every* mention of the "new" Hansaton Free includes laudatory statements regarding the benefits of the open ear configuration (that is, a BTE combined with an open ear receiver) thus supporting the nonobvious of the pending claims. Such laudatory statements are highlighted (emphasis added) in each of Exhibits 7 – 9 which state, for example:

<u>Exhibit</u>	<u>Statement</u>
7	<p>"Free VC Open: Delivery has started, <i>the interest and demand from all our customers side is enormous</i>, as well as our backlog of booked orders! We expect to have full ability of supply by mid of April."</p>
8 p.1	"Free." (large font)

"Experience the future superlative sound with the innovative natural technology."

"...receiver placed directly in the ear canal with its almost invisible link..."

p.2 "Open." (large font)

"Open design and maximum wearing comfort – *the trademarks of the FREE SOUNDMANAGER.*"

"The "open" design...offers you...a very natural sound"

9 p.1 "...feel free" (large font)

p.3 **"Airy. Open."** (large font)

p.7 "...only instrument to combine two benefits...top of the range audiological performance...virtually invisible..."

p.9 "FREE SOUNDMANAGER – *anything but ordinary*" (large font).

"Open shape and maximum wearing comfort are the trademarks of the FREE SOUNDMANAGER" (large font)

"Its new design means that unpleasant occlusion effects and pressure points do not occur at all."

p.14 "Airy." (large font)

p.18 "Open"

"External receiver concept"

p.19 "Open" (large font)

"...does not have the negative effects of an occluded ear as classic systems do."

"External receiver concept" (large font)

"As the auditory canal is not blocked with the external receiver, a natural, balanced tone results."

As is clear from my the above, Hansaton has *repeatedly and continuously* designated the open ear hearing system as "New" and important and as a significant

advance (i.e., "the future") in the field of hearing aids. These laudatory statements exist despite the fact that various different types of hearing aids, including BTE, CIC, ITE and ITC hearing aids, have been known for decades prior to introduction of the Vivotone open ear hearing aid system. It is reasonable to conclude therefore that the presently described open ear hearing aid is non-obvious. Had it been obvious, then it would be irrational for Oticon to be highlighting to the commercial public that such feature is "New" or that such features sets forth a significant advance in the field of hearing aids. Indeed, the fact that Oticon highlights these features as being "New" and significant coupled with the fact that BTE, CIC (even vented CIC units), ITC and ITE hearing aids per se have been known for decades again further evidence that in the field of hearing aids, the idea of this suspended, open ear speaker combined with the behind the ear amplifier and microphone was not obvious until this invention was made by Vivotone.

As noted in detail above (with regard to Oticon), Hansaton *exactly copies* Vivotone's claimed open ear hearing design (note that due to the close similarity of Hansaton's design to Oticon's and Vivotone's, we believe that the Hansaton Free will also generate about three decibels or below of insertion loss over human ear audible frequencies) and *extolls the same virtues* (Hansaton not only references the open ear configurations and external receivers as primary saleable features, but also as a new design leading into the future of superlative sound) claimed in Vivotone's present application. There can be no doubt that there is clear nexus between Hansaton's copying and laudatory statements and Vivotones hearing aid and claim limitations. This is strong evidence of the non-obviousness of Vivotone's pending claims.

As noted above, as noted above, the *Vivotone product addresses/solves the long felt needs* of the industry and indicates that the open ear design (as it is claimed herein). This is also strong evidence of the nonobviousness of Vivotone's pending claims.

Also, as noted above, *Vivotone has had great commercial success* (going from no sales to over eighteen million dollars in sales in two years on the market). This is further strong evidence of the nonobviousness of Vivotone's pending claims.

It should again (with regard to Hansaton) be strongly emphasized that this evidence of nonobviousness should not be discounted (e.g., such evidence is sometimes

rebutted where there is no "nexus" between the claim limitations and the copying or laudatory statements, or where commercial success is attributed to significant advertising efforts or significant reputation in the industry). As noted above, there is *clear nexus* between the present claim limitations and BOTH the copying and the lauded features of the Hansaton device. Also, Vivatone was completely unknown prior to introduction of its open ear hearing aid system. According, name recognition cannot come into play to challenge the evidence of nonobviousness. Finally, Vivatone's advertising was extremely minimal (As noted above, Vivatone did not engage in any television or radio advertising, and only minimal other national advertising; National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal). Accordingly (and to re-iterate the above), the evidence of non-obviousness presented herein and with the Declaration of Leon Hirsch should not be discounted or diminished in any way.

Based on the foregoing, it is submitted that strong evidence of nonobviousness in the form of the Leon Hirsch Declaration and the secondary considerations of nonobviousness has been provided herein.

EACH Of The Categories Of Evidence Of Secondary Consideration Require Separate And Additional Consideration

The Applicants recognize that strong evidence of non-obviousness exists by virtue of the large success of the product in the marketplace (despite the fact of only minimal national advertising), direct copying by large competitors, laudatory statements within the marketing literature of the competitors themselves, which characterize the Applicant's invention as "innovative" and as a "new category" of hearing aid devices and long felt need in the industry.

It must be stressed again that each of the other categories of evidence (commercial success evidence having been discussed above), including 1) evidence of copying, 2) evidence of laudatory statements by competitors, and 3) long felt need in the industry, deserves separate consideration with regard to the claims. That is, any one of the four categories of secondary consideration evidence may show the non-obviousness

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of the claim. Accordingly, each of the four categories deserves separate consideration with regard to the claims.

Review of the Exhibits shows subsequent competitor devices having the same configuration as the commercial Vivotone devices (see Vivotone's device at Exhibit 2, Oticon's device at Exhibit 4, and Hansaton's device at Exhibit 8), with the behind the ear (BTE) processing and microphone sampling, intermediate electrical connection from the BTE to the receiver in the ear and the receiver suspended in the ear canal in an open ear configuration.

As noted in detail above, Hansaton and Oticon exactly copy Vivotone's claimed open ear hearing aid system and extolls the same virtues (as not only primary salable features, but as new innovations in hearing aid technology leading consumers into the next generation of hearing aids) claimed in Vivotone's present application.

Also, as noted above, Vivotone has had great commercial success (going from no sales to over eighteen million dollars in sales in two years on the market), despite no prior reputation, name recognition, or significant advertising efforts. This is further strong evidence of the nonobviousness of Vivotone's pending claims.

There also can be no doubt that there is *clear nexus* between Oticon's copying and laudatory statements and Vivotone's hearing aid and claim limitations.

Further, as noted above, as noted above, *Oticon and Hansaton themselves call out the long felt needs of the industry* and indicate that the open ear design (which is in accordance with the pending claims) solves all of these problems (as it ushers the hearing aid industry into the "next generation"). This is also strong evidence of the nonobviousness of Vivotone's pending claims.

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If there are any charges with respect to this amendment or the Declaration of September 13, 2006 filed herewith, please charge them to Deposit Account 06-1130, maintained by the Applicant's attorneys.

Respectfully submitted,

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Dated: September 14, 2006